IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LOREM VASCULAR, Pte. Ltd., a Singapore Company, Plaintiff, v. PLUS THERAPEUTICS, INC., f/k/a CYTORI THERAPEUTICS, INC., a Delaware Corporation; and DOES 1 through 30, inclusive, Defendants.	C.A. No. 21-885-MN

DEFENDANT'S OPENING BRIEF IN SUPPORT OF ITS
MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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I. INTRODUCTION

This lawsuit is a misguided and futile effort to rewrite a fully integrated agreement between sophisticated companies. On March 29, 2019, Lorem Vascular, Pte. Ltd ("Lorem") and Plus Therapeutics, Inc. f/k/a Cytori Therapeutics, Inc. ("Plus") entered an Asset and Equity Purchase Agreement ("APA") in which Lorem acquired assets related to Plus's cell therapy business for approximately $4 million. These assets included Plus's rights to a facility in the UK used to assemble certain cell therapy products, which Plus disclosed in the APA was "***[n]ot in compliance***" because it "***was supposed to perform an audit of the UK facility last year***" which "***ha[d] not been done yet.*** As a result, Inventory assembled in the UK facility ***cannot be exported to the UK or EU***." D.I. ¶ 19(ii) (emphasis added). The APA also included "a complete and accurate list" of each regulatory authorization Plus held relating to the acquired business. That list did not include any CE certificates covering the products assembled by the UK-based business acquired by Lorem. Lorem acquired the rights to the business and facility anyway.

For over eighteen months after the APA was signed, Lorem did not raise any issue with Plus regarding any purported breach of the APA or any CE certification issues. Then, out of the blue, Lorem wrote to Plus in October 2020, claiming that the APA had been breached because a CE certificate covering the products assembled at the UK facility had been invalid since 2018. Each of Lorem's claims, however, are based on the incorrect premise that Plus somehow led Lorem to believe that CE certification was valid—a premise dispelled by the plain language of the APA. There is no provision in the APA requiring a valid CE certificate covering the UK facility, and Lorem does not identify any such requirement in its Complaint. Faced with the fact that the plain language of the APA directly contradicts its allegations, Lorem resorts to vague allegations about unspecified oral statements or a shipment of products to China that purportedly failed to comply with unspecified regulations. These allegations lack the requisite particularity to satisfy the Rule 9

pleading requirements for its claims—all of which sound in fraud—but even under Rule 8, Lorem fails to state any claim upon which relief can be granted. The Complaint should be dismissed.

II. SUMMARY OF ARGUMENT

All of Lorem's claims against Plus fail, under Rules 8(a) and 9(b), because: (1) the breach of contract claim is premised on an issue that was (i) disclosed in and (ii) not required by the APA; (2) the breach of the implied covenant of good faith and fair dealing claim fails to plead breach of any implied terms; (3) the fraudulent inducement claim is based on vague allegations that do not identify any false statements and cannot support justifiable reliance, and (4) the negligent misrepresentation claim does not plead the existence of the relevant duty or any false statements.

III. STATEMENT OF FACTS[1]

Plus develops clinical-stage pharmaceutical products with a focus rare cancers. D.I. 1 ¶ 8. One of the products Plus developed was the Celution system, which includes a device and various consumables and reagents. *Id.* ¶ 13. The Celution system is used to extract, wash, and concentrate stromal stem cells and other types of cells from adipose (fat) tissue so that it can be re-implanted or re-infused in patients for, among other things, treating wounds. *See id.* Ex. A.

In 2014, Plus entered into an amended 30-year license and supply agreement with Lorem, a regenerative medicine company based in Singapore. D.I. 1 ¶¶ 2, 7; RJN Ex. 2. In that agreement, Plus licensed to Lorem rights to sell and use the Celution system in various countries, including China, and agreed to supply product to Lorem. *Id.*; *Lorem Vascular, Pty. Ltd. v. Cytori Therapeutics, Inc.*, No. 18 Civ. 815 MMA (MDD), 2018 WL 3388096, at *1 (S.D. Cal. July 11, 2018).[2]

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[1] Plus's citation of allegations in the Complaint in the context of this motion should not be interpreted as an admission that the allegations are true.

[2] Lorem filed a similar complaint in 2018 alleging the existence of verbal agreements modifying the terms of the existing written, integrated agreements between the parties. *Lorem Vascular*, 2018

On March 29, 2019, Plus sold its equity interests in Cytori UK[3] to Lorem, including its rights to various assets related to the Celution system as well as leases and property relating to the UK facility, for $4 million pursuant to the APA. *See, e.g.* D.I. 1 ¶¶ 1, 29; RJN Ex. 1.[4] The parties began preliminary negotiations in 2018, and by early 2019, Plus provided Lorem access to diligence documents. *Id.* ¶ 18. During this process, Plus expressly disclosed to Lorem that its UK facility (known as the Deeside facility, where Plus assembled portions of the Celution system) was "***[n]ot in compliance***." D.I. 1 ¶ 31(v); RJN Ex. 1 at Disclosure Schedule § 3.10(b). Plus explained in Disclosure Schedule Section 3.10(b) that "the ***Company was supposed to perform an audit of the UK facility last year*** [*i.e.*, in 2018]. ***This has not been done yet.*** As a result, Inventory assembled in the UK facility ***cannot be exported to the UK or EU***." *Id.* (emphasis added). That Disclosure Schedule also attached CE certificates comprising "a *complete and accurate list* of each Permit relating to the Business held by Seller [Plus] and Cytori UK."[5] *See* RJN Ex. 1 § 3.10(b) (emphasis added); *see also id.* at Disclosure Schedule § 3.10(b) & Ex. 3.10(b); D.I. 1 ¶ 31(v). Plus represented and warranted that each Permit attached to the Disclosure Schedule was "valid and in full force and effect," and "*[e]xcept as set forth in Section 3.10(b) of the Disclosure Schedule*," Plus was "in full compliance with all of the material terms and requirements of each Permit" attached. RJN Ex. 1 § 3.10(b) (emphasis added); *see also* D.I. 1 ¶ 31(v). The attachments to

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WL 3388096, at *1. The court, applying Delaware law, dismissed Lorem's claims, noting that Lorem has failed to allege a scenario whereby an alleged oral agreement could modify the terms of these integrated agreements that required modifications to be in writing. *Id.* at *7-8.

[3] Cytori Ltd., also known as "Cytori UK," was a UK company owned by Plus. RJN Ex. 1 at 1.

[4] Lorem did not attach the APA to its complaint, but as explained in Plus's accompanying Request for Judicial Notice, the APA is incorporated by reference into the Complaint and subject to judicial notice, and is properly considered by the Court with this motion.

[5] "Permit" is defined in the APA to mean "all approvals, authorizations, clearances, notifications, consents, licenses, registrations, permits, permit applications, and any other rights issued, granted, given or otherwise made available by or under the authority of any Governmental Authority or pursuant to any Law." *See* RJN Ex. 1 § 1.01.

Disclosure Schedule Section 3.10(b) did not include the CE certificates for products assembled by Cytori Ltd. at the UK facility that form the basis of Lorem's Complaint. RJN Ex. 1 § 3.10(b). Plus thus represented to Lorem in the fully integrated APA that it had no valid CE certificate covering the products assembled at the UK facility and no authorization to place the products on the market in the UK and EU. *See id.*; *see also id.* §§ 11.05, 11.07.

Indeed, in January 2018, Plus had agreed with its Notified Body to suspend the CE certificates covering the products assembled by Cytori Ltd. at the UK facility because it had not been able to conduct certain audits.[6] D.I. 1, Ex. C. As a result, Plus was not permitted to place a CE Mark (*i.e.*, an indication of a valid CE certificate covering the product) on any products that had been covered by those certificates, and the European Notified Body was notified of the suspension. *Id.* In August 2018, the CE certificates for Cytori Ltd. were cancelled, and the European notified body was again notified. *Id.* Ex. D. As a result of these events, the UK facility was not in compliance, had not completed required auditing, and was not permitted to place the product on the market in the UK or EU, as disclosed in Disclosure Schedule 3.10(b) of the APA.

Several months later, in March 2019—and for the first time since Lorem had last placed an order to purchase Celution system products in April 2015—Lorem sent Plus a purchase order requesting shipment of the consumable set and a reagent to China. D.I. 1 ¶ 19(iii), Ex. B. Plus complied. *Id.* ¶ 3. Lorem does not allege that Plus placed a CE Mark on the shipped products or stated that a valid CE certificate for Cytori Ltd. covered this shipment, and the invoice and packing list with the shipment makes no mention of CE certification. *Id.* Ex. B. Lorem also does not allege that any regulatory or governmental body initiated any action with respect to that shipment.

[6] A Notified Body is an organization that is designated by an EU member state to assess whether products conform to regulations and requirements before being placed on the market. In this case, the notified body was BSI Group. *See* D.I. 1 Ex. C.

IV. LEGAL STANDARDS

Rule 12(b)(6) requires dismissal of claims that fail to allege sufficient factual matter to state a claim for relief that is plausible on its face. *Williams v. BASF Catalysts LLC*, 765 F.3d 306, 315 (3d Cir. 2014). Alleging "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is not enough. *Davis v. Abington Mem'l Hosp.*, 765 F.3d 236, 241 (3d Cir. 2014). The Court is "not required to credit bald assertions or legal conclusions improperly alleged in the complaint." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.,* 311 F.3d 198, 216 (3d Cir. 2002).

When a Complaint avers fraud, Rule 9(b) also requires that a plaintiff state the "with particularity…circumstances constituting fraud" Fed. R Civ. Proc. 9(b). Rule 9(b) applies to "cases where the gravamen of the claim is fraud even though the theory supporting the claim is not technically termed fraud." *Toner v. Allstate Ins. Co.*, 821 F. Supp. 276, 283 (D. Del. 1993) (dismissing breach of the covenant of good faith and fair dealing claim for failure to meet heightened pleading requirements under Rule 9(b)). To satisfy Rule 9(b), a complaint must plead specifics including the '"who, what, when, where and how' of the events at issue . . . [and] specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Vatidis v. Trimble, Inc.*, No. 18 Civ. 998 (MN), 2019 WL 3546693, at *3 (D. Del. Aug. 5, 2019) (dismissing fraud claim) (citing *Institutional Inv'rs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009)).

Courts do not "read [a] complaint in a vacuum and may consider the pleadings, the public record, and other documents incorporated by reference in the complaint." *Daoud v. City of Wilmington*, 894 F. Supp. 2d 544, n.6 (D. Del. 2012); *see also In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 221 (3d Cir. 2002) (affirming dismissal and finding that documents incorporated by reference "fail[ed] to substantiate the Shareholders' claims"). As set forth in Plus's RJN, the APA is the basis for Lorem's claims and is properly considered on this motion to

dismiss. *See, e.g.*, *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.").

V. ARGUMENT

A. Lorem Fails To State A Claim For Breach Of Contract

Basic contract law requires Lorem to identify with specificity a contractual obligation in the APA that Plus allegedly breached. *See FinancialApps, LLC v. Envestnet, Inc.,* No. 19 Civ. 1337(CFC)(CJB), 2020 WL 4569466, at *3 (D. Del. July 30, 2020)*, report and recommendation adopted,* No. 19 Civ. 1337(CFC)(CJB), 2020 WL 5552456 (D. Del. Sept. 15, 2020); *see also Lorem Vascular*, 2018 WL 3388096, at *3 (dismissing breach of contract claim brought by Lorem against Plus). Lorem fails to do so, and its claim for breach of contract should be dismissed.

1. The Plain Language Of The APA Precludes Lorem's Breach Theory

Lorem's entire theory of breach is premised on its allegations that Celution system products assembled at the UK facility were not covered by a valid CE certificate, which was allegedly inconsistent with various representations and warranties in the APA. *See, e.g.*, D.I. 1 ¶¶ 1, 3-6, 15-21, 23-28, 30, 33-37, 43. That theory, however, is directly contradicted by the APA itself.

As explained above in Section III, Disclosure Schedule 3.10(b) states that, as of March 29, 2019, the CE certification was "***[n]ot in compliance***," that auditing required in 2018 "***ha[d] not been done yet***," and that "***[i]nventory assembled in the UK facility cannot be exported to the UK or EU***." RJN Ex. 1 at Disclosure Schedule § 3.10(b) (emphasis added); *see also* D.I. 1 ¶ 19(ii). This Disclosure expressly qualified Plus's representations and warranties in Section 3.10(b). In any event, Plus did not include a CE certificate covering the products assembled by the UK facility in its "complete and accurate" list of all Permits relating to the business that were "valid and in full force and effect." RJN Ex. 1 § 3.10(b), Disclosure Schedule Ex. 3.10(b); D.I. 1 ¶ 31(v). The

APA is clear that Plus's Disclosures in Schedule 3.10(b) also qualify its representations and warranties that may relate to regulatory compliance of the UK facility and any products exported from that facility. *See* RJN Ex. 1 at Art. III ("Disclosures in any section or paragraph of the Disclosure Schedule are made generally and shall not only address the corresponding section or paragraph of this Agreement, but also other sections or paragraphs of this Agreement" if readily apparent from the face of the disclosure that it applies.); *see also Coca-Cola Bottling Co. v. Coca-Cola Co.*, 769 F. Supp. 671, 706 (D. Del. 1991), aff'd, 988 F.2d 414 (3d Cir. 1993) ("[T]he contract should be interpreted as a whole."); *In re G-I Holdings, Inc*., 755 F.3d 195, 202 (3d Cir. 2014) ("[A] a court must construe the agreement as a whole, giving effect to all provisions therein.").

Based on these representations, warranties, and disclosures in the APA, Lorem was well aware that no valid CE certificate covered the products assembled at the UK facility. Lorem is a sophisticated contracting party that was represented by counsel. *See* RJN Ex. 1 at § 11.02. If a valid CE certificate covering the products assembled at the UK facility was a "deal breaker" for Lorem (*see* D.I. 1 ¶ 3), it should have required that language to be added to the APA. It did not, and the APA contains no such representation or requirement. *See REI Holdings, LLC v. LienClear - 0001, LLC*, No. 18-1401 (MN), 2019 WL 3546881, at *9 (D. Del. Aug. 5, 2019) ("[I]t is not the job of a court to relieve sophisticated parties of the burdens of contracts they wish they had drafted differently but in fact did not"); *see also Coca-Cola Bottling Co.*, 769 F. Supp. at 693 (concluding that the fact that the parties were aware of a circumstance at the time of contracting and could have provided for it but did not show they intended not to include it). Lorem's theory of breach is thus precluded by the express language of the APA and should be dismissed.

2. Lorem Fails To Allege Breach Of Any Specific Representations And Warranties

Lorem's more specific allegations of breach fare no better. Lorem takes a kitchen-sink

approach, selectively quoting from nine representations and warranties in the APA that Plus allegedly breached because there was no valid CE certificate covering Celution system products assembled at the UK facility. D.I. 1 ¶¶ 31, 36. Most have nothing to do with CE certification, and none contain any statement that a valid CE certificate covered the UK facility. As explained below, Lorem does not plausibly allege under Rule 8(a)—and certainly not with the particularity required by Rule 9(b)—why any of Plus's representations and warranties were false when made.

a. Section 3.01

In Section 3.01 of the APA, Plus warranted, among other things, that:

> Each of [Plus] and Cytori UK is an entity duly incorporated, validly existing, and, where applicable, in good standing under the laws of the jurisdiction of its incorporation and ha[d] all necessary corporate power and authority to enter into this Agreement and the Ancillary Agreements, to carry out its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby and to conduct its business as it is now being conducted . . . .

D.I. 1 ¶¶ 31(i), 36(i); RJN Ex. 1 § 3.01. Lorem does not allege, nor can it, that Plus was not in good standing or authorized to conduct business under the laws of Delaware. *See* D.I. 1 ¶¶ 8; 36(i). Nor does Lorem allege that Cytori UK, a private limited company registered in the UK (*see* RJN Ex. 1 at Recitals), was not in good standing in any jurisdiction.

Lorem's only allegation of breach is the conclusory statement that Plus was not authorized to conduct business because it "was not authorized to sell or export product shipments to China without a valid CE certificate in place." *Id.* ¶ 36(i). No allegations indicate what specific laws or regulations would have required a valid CE certificate for Plus to sell or export the Celution system products assembled at the UK facility in China. *See* D.I. 1 ¶¶ 13-17 (purporting to summarize EU and Chinese law without citing to any specific law or regulation).[7] In any event, this representation

[7] Plus denies that the shipment of products to China in March 2019 to fulfill Lorem's purchase order violated or was prohibited by any UK, EU, or Chinese laws or regulations.

and warranty about Plus's and Cytori UK's "*corporate power* and authority and qualification" to operate their businesses and enter into the APA has nothing to do with regulatory authorization to sell or export certain products to China. RJN Ex. 1 § 3.01 (emphasis added). Even if it did, the disclosure that no valid CE Certificate covered the Celution system products assembled at the UK facility would qualify this provision. *See, supra*, Section V.A.I.

b. Section 3.06

In Section 3.06, Plus warrants, among other things, that its:

> Books and Records relating to the Business in the Territory, all of which have been made available to Buyer as of the date hereof, are complete and correct in all material respects and represent actual, bona fide transactions and have been maintained in accordance with sound business practices.

D.I. 1 ¶¶ 31(ii), 36(ii); RJN Ex. 1 § 3.06. The APA's definition of Books and Records explicitly excludes regulatory files like CE certificates. RJN Ex. 1 § 1.01 (Books and Records means "books of account, general, financial records, invoices, shipping records, supplier, correspondence and other documents, records and files, sales and promotional literature, customer lists and other sales related materials, electronic mail, electronic records, all other books and records of Seller and any rights thereto, in each case, *excluding the Clinical Files*,[8] any Contracts and any Plans" (emphasis added)). Plus could not have breached this "Books and Records" provision, as Lorem alleges, by "not truthfully disclos[ing]" facts relating to the cancelation of CE certificates for the UK facility, or the regulatory process and timing associated with restoring or reactivating the certificates. *See* D.I. 1 ¶ 36(ii). Regardless, Lorem does not allege that Plus's books and records did not maintain complete and correct documentation of the regulatory status of the UK facility, which was explicitly disclosed in the APA. RJN Ex. 1 at Disclosure Schedule § 3.10(b).

[8] "Clinical Files" is defined to include "all clinical and regulatory files." *Id.*

c. Section 3.08

In Section 3.08, Plus warrants that:

> *Since the Reference Date*, except as set forth in Section 3.08(a) of the Disclosure Schedule, the Business and the Business of Cytori UK has been conducted in the Ordinary Course of Business and there has not occurred any (i) Material Adverse Effect, (ii) transfer, assignment, sale or other disposition of any asset that would be a Purchase Asset . . . or (iii) material damage, destruction or loss, or any material interruption in use, of any Purchased Asset, whether or not covered by insurance, or any changes in the amount or scope of insurance coverage.

D.I. 1 ¶¶ 31(iii), 36(iii); RJN Ex. 1 § 3.08(a) (emphasis added). This section only relates to Plus's Business *since the Reference Date of December 31, 2018*. *See* RJN Ex. 1 § 1.01 (defining "Reference Date"). Omitting the portion italicized above, Lorem alleges that Plus did not conduct Business in the Ordinary Course, and that there had been a material loss because Plus did not have valid CE certificates for the UK facility and illegally shipped products to China without a valid CE certificate. D.I. 1 ¶¶ 36(iii). But the Complaint alleges that the lapse in that CE certificate occurred in January 2018—nearly a year before the Reference Date—and alleges no other "material damage, destruction or loss, or any material interruption in use" between December 31, 2018 and March 29, 2019 when the APA was signed. D.I. 1 ¶ 20(i), Exs. B and C. And for the reasons explained above in Section V.A.2.c, Lorem's vague and conclusory allegation that Plus "knowingly and illegally" shipped products to China is inadequate to establish the illegality of that shipment, and fails to allege how that action violated Section 3.08. D.I. 1 ¶ 36(iii).

d. Section 3.10(a)

In Section 3.10(a), Plus warranted, among other things, that:

> Except as set forth in Section 3.10(a) of the Disclosure schedule, each of [Plus] and Cytori UK (i) has conducted and continues to conduct its business in accordance with all Laws and Governmental Orders applicable to the Business in all material respects, . . . and (iii) no event has occurred or circumstance exists that (with or without notice or lapse of time) may constitute or result in a material violation by [Plus] or Cytori UK, or a material failure of [Plus] or Cytori UK to comply with, any Law with respect to the Purchased Assets or the Business.

D.I. 1 ¶¶ 31(iv), 36(iv); RJN Ex. 1 § 3.10(a). Yet again, Lorem alleges that Plus breached these representations because Plus failed to maintain valid CE certificates for the UK facility and shipped products to China without a valid Free Sale or CE certificate. D.I. 1 ¶¶ 36(iv). Nowhere does Lorem allege that merely not having a valid CE certificate violated any law or governmental order, but in any event, Plus disclosed that its UK facility was not in compliance in Disclosure Schedule 3.10(b). And as explained above in Section V.A.1, Lorem's vague and conclusory allegations about the March 2019 shipment to China do not establish violation of any law or governmental order. That is because Plus was not legally required to maintain a CE certificate, and in any event it disclosed the lack of compliance in Disclosure Schedule Section 3.10(b) .

e. Section 3.10(b)

In Section 3.10(b), Plus represented, among other things, that:

> Section 3.10(b) of the Disclosure Schedule contains a complete and accurate list of each Permit relating to the Business held by [Plus] and Cytori UK. Seller has made available to Buyer complete copies of all such Permits. Each Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule is valid and in full force and effect. Except as set forth in Section 3.10(b) of the Disclosure Schedule, (i) Seller . . . is and has been since the Reference Date, in full compliance with all of the material terms and requirements of each Permit identified . . . . The Purchased Permits listed in Section 3.10(b) of the Disclosure Schedule collectively constitute all of the Permits used by Seller (or, as applicable, Cytori UK) to lawfully conduct and operate the Business in the Territory in the manner in which it currently is conducted.

D.I. 1 ¶¶ 31(v), 36(v); RJN Ex. 1 § 3.10(b).[9] As discussed in Section V.A.1, Disclosure Schedule 3.10(b) does not list the CE certificate covering the UK facility as a valid Permit, and explicitly disclosed that the CE certificate was "not in compliance." The allegation that the "Cytori UK facility would have to restart the entire CE certification process over from scratch" is irrelevant,

[9] Lorem also vaguely alleges that Plus omitted "several other valid and material permits and licenses that were required to have been listed." D.I. 1 ¶ 36(v). Lorem cannot meet its basic pleading obligations under Rule 8(a)—let alone the heightened pleading requirements for this claim sounding in fraud—without identifying these other purported "valid and material permits."

as it does not allege that any of Plus's actual promises were false. *See* D.I. 1 ¶ 36(v). Indeed, Plus made no representation about how the UK facility could be made to comply.

f. Section 3.10(c)

In Section 3.10(c), Plus warranted that:

> All applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, *utilized as the basis for or submitted in connection with any and all requests to obtain or maintain any Purchased Permits from, or otherwise* submitted to, the U.S. Food and Drug Administration (the "FDA") or other Governmental Authority, when submitted to the FDA or other Governmental Authority were *(to the Knowledge of Seller in the case of any such materials prepared by a third party)* true, complete and correct in all material respects as of the date of submission and any legally necessary or required updates, changes, corrections or modifications to such applications, submissions, information, claims, reports or statistics have been submitted to the FDA and other Governmental Authorities.

D.I. 1 ¶¶ 31(vi), 36(vi); RJN Ex. 1 § 3.10(c) (emphasis added). Lorem omits the italicized language above, and vaguely alleges that Plus breached this section because its "submissions to governmental entities were not true and correct because Plus's CE certificates required for exporting products to China were no longer valid." D.I. 1 ¶ 36(vi). Lorem fails to identify any "submissions" or "governmental entities," or how unidentified "submissions" were purportedly false. Indeed, the Complaint Exhibits demonstrate that Plus *did* notify BSI (a notified nody), who notified the Competent Authority and European Database. D.I. 1 at Ex. D. And the Complaint certainly does not allege a submission utilized as the basis for or submitted in connection with a request to obtain or maintain a Purchased Permit that was false *as of the date of submission*.

g. Section 3.10(d)

In Section 3.10(d), Plus warranted, among other things, that:

> Other than as set forth in Section 3.10(d) of the Disclosure Schedule, neither [Plus] nor Cytori UK is aware, nor has it received notice, of any Action pending with respect to a violation by [Plus] or Cytori UK of the FDCA or other Law, and, to the

> Knowledge of [Plus], there are no facts or circumstances existing that would reasonably be expected to serve as a basis for such an Action."[10]

D.I. 1 ¶¶ 31(vii), 36(vii); RJN Ex. 1 § 3.10(d). Lorem alleges this representation is false because Plus was aware that the UK facility was not CE compliant—a fact that Plus disclosed in Disclosure Schedule 3.10(b)—and because of the March 2019 shipment to China without a valid CE certificate. Lorem does not allege that Plus or Cytori UK had received any notice of any pending Action, and its conclusory allegations contain no facts indicating that either event "would reasonably be expected to serve as a basis for" an Action. More than two years have passed since the representations in Section 3.10(d), and Lorem does not allege that any Action has materialized.

h. Section 3.10(e)

In Section 3.10(e), Plus warranted, among other things, that:

> No Governmental Authority has commenced or, to the Knowledge of Seller, threatened to initiate any action to request the recall of any products produced thereunder nor has Seller or Cytori UK received any notice to such effect and, to the Knowledge of Seller, there are no grounds for such action."

D.I. 1 ¶¶ 31(viii), 36(viii); RJN Ex. 1 § 3.10(e). Lorem vaguely alleges this representation is false because Plus did not state that the UK facility was "not CE compliant" and violated export laws by shipping products to China. D.I. 1 ¶ 36(viii). Again, Plus disclosed that the UK facility was not CE compliant in Schedule 3.10(b). Lorem also fails to allege anything beyond conclusions to establish that these circumstances would be *grounds for a product recall*. More than two years have passed, and Lorem has no allegation that any Government Authority has threatened or initiated any recall proceedings affecting products assembled or shipped from the UK facility.

[10] "Action" is defined in the APA as "any claim, action, grievance, suit, arbitration, inquiry, proceeding, investigation, audit, hearing or litigation by or before any Governmental Authority or arbitrator." RJN Ex. 1 § 1.01.

i. Section 3.15

In Section 3.15, Plus warranted, among other things, that:

> Except as set forth in Section 3.15 of the Disclosure Schedule, the Purchased Assets and the assets of Cytori UK (a) constitute all of the assets, tangible and intangible, of any nature whatsoever, used to operate (and to the Knowledge of Seller, necessary to operate) the Business in the Territory in the manner presently operated by Seller and Cytori UK, and as has been conducted in the past year, in the Territory . . . .

D.I. 1 ¶¶ 31(ix), 36(ix); RJN Ex. 1 § 3.15. While Lorem alleges this representation was false because it does not state that the UK facility lacked valid CE certificates and thus could not export in the UK—facts Plus disclosed in Disclosure Schedule 3.10(b)—it does not allege any facts establishing that the Purchased Assets did not include all of the assets that Plus used to operate the business *in the previous year*. Lorem itself alleges that the CE certificates for the UK facility were suspended in January 2018, *i.e.*, more than a year before the APA was signed. D.I. 1 ¶ 20(i).

For all of the foregoing reasons, Lorem fails to allege—under Rule 8(a) or 9(b)—any breach of contract by Plus, and that claim should be dismissed.[11]

B. Plaintiff Fails to State a Claim for Breach of Implied Covenant of Good Faith and Fair Dealing

Lorem's breach of implied covenant claim fails because it does not allege any specific implied obligation of the APA that Plus breached. *See S. Track & Pump, Inc. v. Terex Corp.*, 623 F. Supp. 2d 558, 562 (D. Del. 2009). Application of the implied covenant is a "limited and extraordinary legal remedy." *See, e.g.*, *Glaxo Grp. Ltd. v. DRIT LP*, 248 A.3d 911, 920 (Del. 2021). As this Court has explained, "[t]he implied covenant only applies where a contract lacks specific language governing an issue and where the implied term does not override the express

[11] Lorem's claim that Plus breached Section 9.02 by refusing to indemnify is wholly derivative of the alleged breaches of representations and warranties. Because Lorem did not state a claim for breach of a representation and warranty, it did not state a claim for breach of APA Section 9.02.

terms of a contract." *vMedex, Inc. v. TDS Operating, Inc*., No. 18- Civ. 1662 (MN), 2020 WL 4925512, at *8 (D. Del. Aug. 21, 2020) (quotation omitted) (dismissing implied covenant claim because plaintiffs failed to "identify a gap in the APA that the Court should fill with an implied contractual obligation"). It is used to infer contract terms to "deal with unanticipated developments or to fill gaps in [a] contract's provisions . . . but only where it is clear that the parties would have agreed to the obligation had they considered the issue." *Truinject Corp. v. Nestlé Skin Health. S.A*., No. 19 Civ. 592(LPS)(JLH), 2020 WL 70981 at *13 (D. Del. Jan. 7, 2020) (dismissing implied covenant claim because it did not allege an implied term that was not addressed by the express terms)*, report and recommendation adopted sub nom.*, *Truinject Corp. v. Nestlé Skin Health. S.A*., No 19 Civ. 592 (LPS) (JLH), 2020 WL 1270916 (D. Del. Mar. 17, 2020); *see also Winshall v. Viacom Int'l, Inc*., 76 A.3d 808, 816 (Del. 2013) (same). It is not used to infer contract terms when the subject matter is already covered by the express terms of a contract. *Truinject*, 2020 WL 70981 at *13. And if the parties discussed a topic in negotiations, but did not include any explicit promises in the contract regarding the topic, no contract terms will be implied. *See S. Track & Pump*, 623 F. Supp. 2d at 562-63. Indeed, in a prior lawsuit between the parties, the court dismissed a similar claim by Lorem, explaining that the agreement at issue "could have been drafted to expressly provide" the alleged implied term, but was not. *Lorem*, 2018 WL 3388096, at *7.

Lorem does not even attempt to identify an implied contractual obligation, and instead argues that Plus "unfairly interfered with Lorem's rights to receive the benefits of the APA" by "intentionally misrepresenting" the CE certification status of Cytori UK and depriving Lorem of the ability to sell products assembled at Cytori UK and export them. *See* D.I. 1 ¶ 48; *see also id.* ¶¶ 45-50. Nor does Lorem identify any implied terms relating to these allegations, because there is no "gap" to fill. The subject matter of these alleged breaches is expressly covered by Section

3.10(b) and Disclosure Schedule 3.10(b) of the APA. *Truinject*, 2020 WL 70981 at *13. While Lorem alleges that it specifically discussed the CE certification status of the UK facility in negotiations (*see, e.g.*, D.I. 1 ¶¶ 3, 19, 24); no contractual terms may be implied when Lorem failed to include any promises regarding CE certification in the APA. Lorem's implied covenant claim fails to meet the requirements of Rule 8(a), and certainly does not plead breach of any implied terms with particularity as required for Rule 9(b) for claims sounding in fraud.

C. Plaintiff Fails to State a Claim for Fraudulent Inducement

1. Lorem Fails to Plead False Statements with Particularity

Other than Section 3.10(b) of the Disclosure Schedule to the APA, the Complaint fails to allege *a single* purported false statement, much less the date(s) of such statements, the speaker(s), or any other details around them. Lorem's general allegations insinuating that there was some wrongdoing without actually alleging any facts do not meet the particularity requirements of Rule 9(b). *See Kirchner v. Wyndham Vacation Resorts, Inc.*, No. 20 Civ. 436(CFC), 2021 WL 1198314, at *3 (D. Del. Mar. 30, 2021) (dismissing fraud claim when plaintiff failed to state when or where the misrepresentations took place, or the speakers' identities). While Lorem also vaguely references "omissions" (*see* D.I. 1 ¶¶ 53-54), it does not specifically identify any fraudulent omission or allege that Plus Therapeutics "had a duty to disclose" any omitted information. *See vMedex*, 2020 WL 4925512, at *11; *see also REI Holdings, LLC v. LienClear - 0001, LLC*, No. 18-1401 (MN), 2019 WL 3546881, at *6 (D. Del. Aug. 5, 2019) (dismissing fraudulent inducement for failure to allege "that Defendants owed a duty to disclose the allegedly concealed facts").

As for Section 3.10 of the Disclosure Schedule, Lorem alleges that it "falsely indicates that the CE certification for Cytori UK was intact." D.I. 1 ¶¶ 19(ii), 27. That is not at all what Section 3.10 states. As explained further above in Section, V.A.1, Section 3.10 of the Disclosure Schedule attaches "a complete and accurate list" of valid CE certificates, which did not include any CE

certificate for Cytori UK. Lorem also alleges that the explicit disclosure that the CE certificate was "not in compliance" implausibly "created the false impression upon Lorem that the only reason why Cytori UK was not in compliance was because it had not yet completed an audit that was due in 2017, a routine and perfunctory process that takes a few weeks and costs little (*e.g.*, $8,000), and that once Lorem completed the overdue audit after the APA CE compliance would be restored."[12] D.I. 1 ¶ 19(ii). But the Complaint alleges no factual support for this wild inference that Lorem alleges it took from a representation that the UK facility was "[n]ot in compliance" because of an audit that was supposed to be done the prior year.

The rest of the alleged misrepresentations (or inferences that Lorem draws from documents that are not Plus representations) lack the specificity needed to identify them or why they are false:

- D.I. 1 ¶ 19(i): Cytori Ltd.'s CE certificates "appeared valid on their face." The Complaint does not allege how the certificate itself is a misrepresentation, because it is not. And in any event, as discussed above, Disclosure Schedule 3.10(b) did not include this CE certificate, and its noncompliance was expressly disclosed.
- D.I. 1 ¶ 19(iii): Cytori shipped products to China on March 26, 2019 to fulfill Lorem's purchase order, and invoiced Lorem for them. Lorem alleges this "confirmed to Lorem that a valid CE certificate existed."[13] *Id.* Lorem's silent inference about this shipment,

[12] Lorem repeatedly alleges that it understood completing the audits to be "a routine and relatively straightforward matter to correct," but it never attributes that understanding to representations by Plus. *See* D.I. 1 ¶ 19(v); *see also id.* ¶¶ 4, 5, 19(ii), 41, 43.

[13] Lorem alleges the legal conclusion that China "will allow foreign companies to import and market certain medical devices in China provided they are allowed to freely sell such products in the country of manufacture (country of origin)." D.I. 1 ¶ 15. If that were true, then Lorem would have known based on the Section 3.10(b) Disclosure (*i.e.*, no product from the UK facility could be exported to the UK or EU) that no device export would be permitted to China. The Complaint also omits that under the 2014 License, it was *Lorem's* responsibility to gain regulatory approval in China. RJN Ex. 2 at §§ 3.9.2, 3.12.1. Further, there is no allegation that any regulatory authority

however, is not supported by any representation from Plus, and is inconsistent with the disclosure Plus signed just three days later that the UK facility was "[n]ot in compliance" and that, as a result, products could not be exported to the UK and EU. Indeed, the shipping invoices attached to the Complaint make no reference to any CE certification, nor does Lorem allege that that its request for these products demanded CE certification. *See id.* Ex. B. Lorem also alleges no law that the shipment to China purportedly violated.

- D.I. 1 ¶ 19(iv): On a March 26, 2019 teleconference, Cytori's CFO allegedly read a proposed disclosure for Schedule 3.10(b) that "may have effectively excused any failure of the European regulatory status representation and warranty for Cytori UK," which Lorem rejected. Lorem does not allege that the unspecified draft language Cytori's CFO read was false, or any misrepresentation by Plus (or Cytori) during this call.
- D.I. 1 ¶ 19(v): Certain individuals at Lorem allegedly "recall" unspecified "verbal confirmations" from Cytori's CFO that Cytori UK was CE certified, at unspecified times "leading up to the APA." This is inconsistent with APA Section 3.10(b) and the Disclosure Schedule, as discussed in Section V.A.1, and lacks the specificity required by Rule 9(b).

2. Lorem's Fraudulent Inducement Claim Is A Repackaged Breach Of Contract Claim

Lorem's fraudulent inducement claim also fails because it is indistinguishable from its breach of contract claim. Under Delaware law, "[a] breach of contract claim cannot be 'bootstrapped into a fraud claim merely by adding the words 'fraudulently induced' or alleging that the contracting parties never intended to perform ." *Frazier v. Am. Airlines, Inc.*, No. 03-Civ. 734 JJF, 2004 WL 2223298, at *4 (D. Del. Sept. 30, 2004). In other words, a fraud claim may

in China, the UK, or the EU ever indicated that the March 2019 shipment was somehow illegal or improper.

only survive if it "involve violation[s]" of an independent "duty which arises by operation of law and not by the mere agreement of the parties." *Cornell Glasgow, LLC v. La Grange Properties, LLC*, No. 11 Civ.05-016 (JRS), 2012 WL 2106945, at *8 (Del. Super. Ct. June 6, 2012). As discussed above, the only statement Lorem identifies with any level of specificity is Section 3.10(b) of the Disclosure Schedule to the APA (which was not false). Where, as here, a plaintiff bootstraps a fraud-based claim to a breach of contract claim with general, non-particularized allegations, the fraud-based claim should be dismissed. *See Red Mountain Holdings, Ltd. v. Stout P'ship*, No. 00 Civ. 190(JJF), 2001 WL 34368400, at *4 (D. Del. Mar. 30, 2001). Lorem's failure to allege separate damages stemming from its breach of contract and fraudulent inducement claims further raises the inference that the fraud claim is bootstrapped. *See, e.g.*, *EZLinks Golf, LLC v. PCMS Datafit, Inc.*, No. 16 Civ. 07-080 (PRW) (CCLD), 2017 WL 1312209, at *6 (Del. Super. Ct. Mar. 13, 2017) (dismissing fraud claims when "the alleged fraudulent inducement and breach of contract appear materially identical" and alleged fraud damages are indistinguishable).

3. Lorem Cannot Allege Justifiable Reliance

Lorem also does not—and cannot—plausibly allege that it justifiably relied on any alleged "misrepresentations." A plaintiff "cannot recover if [it] blindly relies upon a misrepresentation the falsity of which would be patent to him if he had utilized his opportunity to make a cursory examination or investigation." *Davis v. 24 Hour Fitness Worldwide, Inc.*, 75 F. Supp. 3d 635, 640–41 (D. Del. 2014) (quotation omitted). Indeed, it is not plausible that Plus's alleged "false" statements induced Lorem to enter into the APA, which on its face contains no provision regarding the validity of the CE certificate for the products assembled at the UK facility, and which expressly discloses the CE certificate's noncompliance. *Tracinda Corp. v. DaimlerChrysler AG*, 364 F. Supp. 2d 362, 402 (D. Del. 2005), *aff'd*, 502 F.3d 212 (3d Cir. 2007) (holding that "contradictions in the written agreements compared to . . . alleged oral representations weigh against a conclusion

of reasonable reliance."). This is particularly true in light of the APA's integration clause, which provides that the APA "constitute[s] the entire agreement" between the parties and "supersede[s] all prior agreements and undertakings, both written and oral." *See id.*; RJN Ex. 1 § 11.05.

D. Plaintiff Fails to State a Claim for Negligent Misrepresentation

Finally, Lorem fails to state a claim for negligent misrepresentation because it fails to allege (1) the requisite duty and (2) any false information that Plus provided. "[N]egligent misrepresentation is a viable claim in Delaware only when there is a fiduciary relationship between the parties." *Keystone Assocs. LLC v. Barclays Bank PLC*, No. 19 Civ. 796 (MN), 2020 WL 109008, at *4 (D. Del. Jan. 9, 2020) (quotation omitted). Here, there is no allegation in the Complaint of a fiduciary relationship between the parties, nor is there any allegation of any other facts that would give rise to the requisite duty to support a negligent misrepresentation claim. Further, because Lorem's negligent misrepresentation claim "sounds in fraud," it is required to allege the supplying of false information under Rule 9(b)'s heightened pleading requirements, which it fails to do for the same reasons discussed above. *See Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85-86 & n.3 (3d Cir. 2015) (affirming application of Rule 9(b) to a negligent misrepresentation claims that "sounds in fraud"); *see also Keystone*, 2020 WL 109008, at *4-5; *King v. Pratt & Whitney Can. Corp.*, No. 20Civ. 359(LPS)(CJB), 2021 WL 663059, at *3 (D. Del. Feb. 19, 2021), *report and recommendation adopted*, No. 20 359(LPS)(CJB) (D. Del. Mar. 17, 2021), ECF No. 47

VI. CONCLUSION

For the foregoing reasons, Plus respectfully requests that the Court dismiss the Complaint with prejudice, as amendment would be futile in light of the plain language of the APA.

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